

## TCT-436

**Impact of a Mechanical Circulatory Support Program in the Survival of Patients with Cardiogenic Shock Undergoing Primary Angioplasty.**

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**Background:** Patients in cardiogenic shock benefit from mechanical reperfusion, but their mortality remains high even using intra-aortic balloon. It is not well known if a Mechanical Circulatory Support Program (MCSP) might improve the long term outcome of these patients.

**Methods:** We have compared in-hospital and 1 year survival of patients in cardiogenic shock in the setting of a primary angioplasty with inserted intra-aortic balloon in two different periods of time, before and after the implementation in our hospital of a MCSP. This program included training for staff and the availability of extracorporeal membrane oxygenation device (ECMO) and left ventricular or biventricular assist devices (LVAD, biVAD). Following inclusion criteria were required: STEMI, cardiogenic shock by defined clinical and hemodynamic data, primary angioplasty done and intra-aortic balloon inserted. Patients with cardiogenic shock due to mechanical complications were excluded.

**Results:** We included 42 consecutive patients in the first period "pre-MCSP" and 56 in the second period "post-MCSP". Clinical baseline characteristics were very similar in both groups except for a higher use of drug-eluting stents in the second period (19% vs 40%;  $p=0.03$ ). In the "post-MCSP" group 9 (16%) patients had an ECMO and 8 (14.3%) a ventricular assist device. Six patients were included in the cardiac transplant list in the "pre-MCSP" group and four in the "post-MCSP" group. Three patients in each group finally underwent a cardiac transplant. In-hospital survival was 49.9% in the "pre-MCSP" group compared to 67.2% in the "post-MCSP" group ( $p=0.03$ ). The 12 months survival was 39.8% in the "pre-MCSP" group vs. 59.5% in the "post-MCSP" group ( $p=0.03$ ). The multivariate logistic regression revealed a higher risk of death in the "pre-MCSP" period (HR 2.5; CI 95% 1.04-7.5;  $p=0.04$ ).

**Conclusions:** The implementation of a mechanical circulatory support program improves significantly the prognosis of patients in cardiogenic shock in the setting of a primary angioplasty.

## TCT-437

**Percutaneous atrioseptostomy is a safe and efficient strategy for left heart discharge under veno-arterial peripheral extracorporeal membrane oxygenation**

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**Background:** Veno-arterial Extracorporeal Membrane Oxygenation (VA-ECMO) is a life-saving mechanical support in case of intractable heart failure. It is widely used in both children and adult patients, as a bridge to recovery or heart transplantation. It can lead to increased left atrial pressure, resulting in haemoptysis and severe acute pulmonary oedema. We hypothesized that percutaneous atrioseptostomy (PAS) is a safe and efficient alternative for left heart discharge under VA-ECMO.

**Methods:** A monocenter retrospective study was conducted at our center From April 2008 to April 2013, 160 patients were assisted with peripheral VA-ECMO. Twenty-three of them (1 month to 72 years old, median age: 34 years, 6 children and 17 adults) needed left heart discharge and had a PAS. The procedure was done in the catheterization laboratory under fluoroscopic guidance via the femoral vein and a trans-septal puncture using a Brockenbrough needle. For adult patients, a 28 mm Inoue balloon was inflated across the inter-atrial septum, creating an unrestrictive 30 mm atrial septal defect. Left and right atrial pressures were measured in the cath lab before and just after PAS.

**Results:** Intractable heart failure was due to acute myocarditis ( $n=5$ ), dilated cardiomyopathy ( $n=9$ ), acute coronary syndrome ( $n=4$ ) or post-operative myocardial dysfunction ( $n=5$ ). PAS was performed under local anaesthesia in 9 patients (40%). Median delay from ECMO to PAS was 64 hours (4 to 766 hours). No procedure-related complication was reported. Left atrial pressure significantly decreased after atrioseptostomy, from 22mmHg (5 to 45 mmHg) to 10mmHg (1 to 19 mmHg),  $p<0.001$ . Clinical improvement was observed in 4 of 6 patients with pulmonary haemorrhage and 18 of 22 patients with pulmonary oedema (81, 8%, IC95%[65.7%-97.9%]). At a mean follow-up of  $8.3 \pm 9$ , 2 days after the procedure, two patients were successfully weaned from ECMO, 4 patients had implantation of a left ventricular assist device, 8 were transplanted and 9 patients died under VA-ECMO.

**Conclusions:** PAS is a safe and efficient strategy to discharge the left heart in paediatric and adult patients under peripheral VA-ECMO.

## TCT-438

**Alcohol septal ablation (ASA) for hypertrophic obstructive cardiomyopathy (HOCM) - follow up to 12 years.**

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**Background:** ASA is an established treatment for symptomatic HOCM. The evidence base is limited to case series. ASA has a 2b recommendation in treatment for HOCM from the 2011 ACCF/AHA guidelines. We report a series over 12 years from a high volume UK centre.

**Methods:** All patients referred to our tertiary centre for ASA from 2000-2012 were reviewed. All had peak LVOT gradient  $\geq 50$ mmHg and basal septal diameter  $>15$ mm. No patient had systolic dysfunction. Only those entering the lab with the intention of alcohol delivery were included. 88 patients were identified, mean age 60.3 years. Four patients could not receive alcohol. 20 (24%) required a second procedure with delivery of alcohol, 2 (2%) required a third. Follow up period was 4.2 ( $\pm 3.3$ ) years, range 0.13-12.29.

**Results:** Mean number of arteries injected was 1.13 ( $\pm 0.37$ ), volume of alcohol used was 2.24 ( $\pm 1.08$ ) mL. CK-MB release was 149.6 ( $\pm 135.6$ ) ng/dL. New CHB requiring PPM was seen in 14/74 (17%) patients. One inpatient death followed haemodynamic compromise as a complication of PPM implant. Distal infarction of inferior wall was seen in 1, pericardial effusion without tamponade in 1. Symptomatic follow up was available in 82/84 patients. Mean NYHA class dropped from 2.80 ( $\pm 0.46$ ) to 1.92 ( $\pm 0.84$ ) ( $p<0.0001$ ). 72% patients improved, 26% found no difference, 2% deteriorated. CPEX testing pre and post-ASA with RER  $>1.1$  was available in 24. Peak VO2 improved from 18.9 ( $\pm 4.45$ ) to 20.09 ( $\pm 5.73$ ) mL/min/kg ( $p=0.018$ ). Pre and post echocardiographic assessment was available in 74. 61 had rest LVOT gradient of  $>50$ mmHg, peak 99.8 ( $\pm 46.1$ )mmHg. Post ASA gradient reduced to 23.9 ( $\pm 41.6$ )mmHg ( $p<0.0001$ ). A further 13 patients had minimal resting gradient but  $>50$ mmHg on exercise, peak value 102.0 ( $\pm 49.6$ ) mmHg. This improved to 16.9 ( $\pm 30.7$ )mmHg ( $p=0.0005$ ). Failure was defined as final gradient  $>50$ mmHg or reduction in gradient  $<50\%$ . This occurred in 13/74 (18%). No sudden death was observed. No appropriate therapy was delivered in 15 with ICD.

**Conclusions:** ASA provides symptomatic improvement and gradient resolution for the majority. However, 5% do not receive treatment, 18% have failure to resolve LVOT gradient and 28% find no improvement in dyspnoea.

## TCT-439

**First Report of Short Term and Long Term Outcomes from a Confirmatory Study of Percutaneous Ventricular Restoration (PVR) therapy using the Parachute® Device in Patients with Ischemic Dilated Heart Failure**

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**Background:** Left ventricle (LV) remodeling after anterior wall myocardial infarction (AWMI) leads to increased LV volumes, myocardial stress, and ultimately heart failure (HF). Treatment options are limited for these high-risk HF patients. First-in-man (FIM) experience of PVR using the Parachute® device suggested the safety of this approach. An ongoing study was designed to validate these observations in an independent cohort of patients.

**Methods:** To confirm the short term and long term efficacy of PVR using an expanded range of Parachute® device sizes in patients with ischemic HF with prior AWMI. Methods: Up to 80 patients with NYHA class II-IV HF secondary to AWMI, with aknetic or dyskinetic wall motion abnormality, LV ejection fraction  $<40\%$ , and without the need for revascularization are being enrolled into this prospective study at 20 European sites. Primary endpoint Major endpoints to report are device-related MACE and death plus hospitalization for worsening heart failure (WHF). A subset of patients (approximately 15) underwent repeat CT imaging at 6 months post implant.

**Results:** As of May 9, 2013, 55 patients had reached 6 month FU and 26 patients had reached 12 month FU. Historical 6-month and 12-month rates of death + WHF for the FIM cohort was 16.1% and 16.1%, respectively. In the present Validation cohort, the 6 month and 12 month rates of death + WHF was 18.9% and 23.7%, respectively. Additionally, the paired CT images will be analyzed and compared to the FIM subset of CT imaging. Follow-up on 80 patients at 6 month and 50 patients at 12 month will be completed by September 1, 2013 and results will be available for presentation.

**Conclusions:** Preliminary results of this confirmatory trial of PVR using an expanded range of Parachute device sizes in an independent cohort of patients with ischemic HF and prior AWMI supports the safety and efficacy of Parachute, thus supporting the conduct of a large RCT.